

REMARKS

I. Introduction.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1 and 31 are currently being amended. Support for the amendment may be found throughout Applicant's specification, e.g., at paragraphs 12 and 93-104. The amendments are made solely in the interest of advancing prosecution, and should not be considered to bear upon the patentability of the claims as previously presented. Applicant reserves the right to pursue the subject matter of the claims, as originally or previously presented, at a later time, e.g., in a continuing application.

No claims are requested to be cancelled.

No claims are being added.

After amending the claims as set forth above, claims 1-26, 31, and 32 are now pending in this application.

II. The Rejections Under 35 USC §102 Should Be Withdrawn.

The Office Action rejects claims 1-5, 7, 9, 13, 14, 17-19, and 22 under 35 USC §102(b) as anticipated by Ogawa U.S. Pat. No. 4,680,445 ("Ogawa"). Applicant Respectfully traverses.

To anticipate a claim, a reference must disclose each and every limitation of the claim. M.P.E.P. §2131. Applicant respectfully submit that Ogawa fails to disclose each and every element of the rejected claims.

Independent claim 1, as amended, recites a system for heating a fluid for delivery into a body of a patient which includes:

an elongated flexible fluid delivery-line comprising:

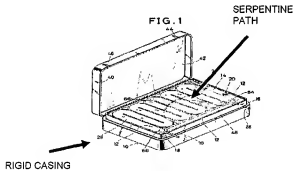
a tube for communicating a fluid;
three or more thermal sensors, at least one thermal sensor positioned approximate to each end of the tube and at least one thermal sensor positioned in between the ends of the tube; and
a heating element positioned proximate a surface of the tube to heat fluid within the tube, the heating element being controlled based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube. (emphasis added.)

For example, in one non limiting embodiment described in Applicant's specification, the flexible fluid delivery-line is advantageously integrated into an intravenous delivery ("I.V.") set (e.g., as commonly found in emergency room or ambulance environments):

an I.V. set [is integrated] with a novel warming method and system, for example...[t]he method and system may...include a delivery-line component between the fluid supply bag and the patient connection. The total length of the delivery-line component may be comprised of a uniform tube construction to warm the fluid along its entire length.

Accordingly, this novel design according to some embodiments of the present invention may allow the fluid delivery pathway to be **flexible, non-kinking, in lengths of one foot and greater. ...[T]he ability of the fluid warmer to act as an I.V. set enable some of the embodiments of the present invention well suited to portability and use in a variety of environments.** Gradual and efficient warming over the entire **non-serpentine fluid delivery length**, for example, may support low and high (1 mL/min to 600 mL/min) flow rates for a variety of parenteral fluids, including whole blood, substantially eliminating or limiting damage to the fluid and/or patient, or overheating. (emphasis added.)

Applicant respectfully submits that Ogawa fails to disclose a flexible elongated fluid delivery line including a heating element and three or more sensors, as required by independent claim 1. To the contrary Ogawa (e.g., as shown in Fig. 1, excerpted and annotated below) describes a fluid warming device in which a fluid to be heated is passed through a heating bag 26 mounted in and having a serpentine liquid passage 34 running through a casing 10. The casing 10 includes a pair of heating plate elements 50 and 52 (e.g., as shown in Fig. 4) for heating the fluid, and a set of thermosensors mounted on the casing for monitoring the fluid temperature.



Note that, even assuming, *arguendo*, that heating bag 26 of the Ogawa device could be identified as an elongated flexible fluid delivery-line, this line does not include any heating elements or thermal sensors. Instead, all heating elements and sensors in the Ogawa device are integrated into the casing 10. (See, e.g., Abstract and column 3, lines 53-68.)

Thus, the device of Ogawa is simply a conventional fluid warming device of the type described in the background section of Applicant's specification (paragraphs 6 -7), which notes that:

prior art references use electrically heated plates in either direct or indirect contact with the fluid to be warmed. The methods and systems available to

suitably warm fluids have several limitations in common. One of the common problems associated with current fluid warmers (a.k.a., "blood warmers") is the lack of portability, in particular the need for an AC power source, or a large, cumbersome battery. **Another common problem with current fluid warmers is the lack of flexibility to specific environments such as ambulances, emergency rooms and field use. Yet another common problem of current fluid warmers relates to fluid flow-rate limitations and associated localized overheating of fluid due to serpentine fluid pathways, or the inefficient application of heat to the fluid.** (emphasis added.)

The Ogawa device requires a rigid casing with heating plates, and thus has a disadvantageously inflexible form factor which may not be suitable to various environments. The device further features a serpentine fluid path that may restrict flow rate. In contrast, embodiments of the claimed device may have a form factor which can be easily integrated into existing fluid delivery set ups (e.g., I.V. sets), and do not require a serpentine fluid path. (See Applicant's specification, paragraphs 10-13).

In view of the above, Applicant respectfully submits that Ogawa fails to disclose each and every element of independent claim 1. Therefore, there is no proper basis for the rejection of claim 1 under 35 USC §102(b). Claims 2-5, 7, 9, 13, 14, 17-19 and 22 each depend, directly or indirectly, from independent claim 1, and therefore distinguish Ogawa for at least the same reasons. Accordingly, Applicant respectfully requests reconsideration and withdrawal of all rejections under 35 USC §102(b).

III. The Rejections Under 35 USC §103 Should Be Withdrawn.

A. Ogawa in view of Swenson

The Office Action rejects claims 6, 8, 24-26, and 31 under 35 U.S.C. §103(a) as unpatentable over Ogawa in view of Swenson U.S. Pat. No. 5,195,976 ("Swenson"). Applicant respectfully traverses.

Initially, Applicant does not concede that the proposed modifications of Ogawa in view of Swenson would have been obvious to a person skilled in the art at the time of the invention. However, even assuming, *arguendo*, that the proposed modifications are proper, Applicant respectfully submits that they fail to teach or suggest each and every limitation of the rejected claims, as required for a proper rejection under 35 U.S.C. §103(a). M.P.E.P. §2141.

Claims 6, 8, and 24-26 each depend, directly or indirectly, from independent claim 1. Thus, each of these claims require an elongated flexible fluid delivery-line which includes a heating element and three or more thermal sensors. Independent claim 31 includes a substantially similar limitation.

As discussed in detail above, Ogawa does not teach or suggest such a delivery-line. Instead, the Ogawa device is a conventional fluid heater, in which fluids are passed through a rigid casing for heating by a set of heating plates. None of the modifications of Ogawa proposed in view of Swenson in the Office Action (pages 5-7) cure this deficiency.

In view of this, Applicant respectfully submits that there is no proper basis for the rejections of claims 6, 8, 24-26, and 31 as unpatentable over Ogawa in view of Swenson. Applicant respectfully requests reconsideration and withdrawal of these rejections.

B. Ogawa in view of Lenker

The Office Action rejects claims 10 and 16 under 35 U.S.C. §103(a) as unpatentable over Ogawa in view of Lenker U.S. Pat. No. 6,746,439 ("Lenker"). Applicant respectfully traverses.

Initially, Applicant does not concede that the proposed modifications of Ogawa in view of Lenker would have been obvious to a person skilled in the art at the time of the invention. However, even assuming, *arguendo*, that the proposed modifications are proper, Applicant respectfully submits that they fail to teach or suggest each and every limitation of the rejected claims, as required for a proper rejection under 35 U.S.C. §103(a). M.P.E.P. §2141.

Claims 10 and 16 each depend, directly or indirectly, from independent claim 1. Thus, each of these claims require an elongated flexible fluid delivery-line which includes a heating element and three or more thermal sensors.

As discussed in detail above, Ogawa does not teach or suggest such a delivery-line. Instead, the Ogawa device is a conventional fluid heater, in which fluids are passed through a rigid casing for heating by a set of heating plates. None of the modifications of Ogawa proposed in view of Lenker in the Office Action (pages 7-8) cure this deficiency.

In view of this, Applicant respectfully submits that there is no proper basis for the rejections of claims 10 and 16 as unpatentable over Ogawa in view of Lenker. Applicant respectfully requests reconsideration and withdrawal of these rejections.

C. Ogawa in view of Shigezawa

The Office Action rejects claims 11, 12, 15, and 23 under 35 U.S.C. §103(a) as unpatentable over Ogawa in view of Shigezawa U.S. Pat. No. 6, 641,566 ("Shigezawa"). Applicant respectfully traverses.

Initially, Applicant does not concede that the proposed modifications of Ogawa in view of Shigezawa would have been obvious to a person skilled in the art at the time of the invention. However, even assuming, *arguendo*, that the proposed modifications are proper, Applicant respectfully submits that they fail to teach or suggest each and every limitation of the rejected claims, as required for a proper rejection under 35 U.S.C. §103(a). M.P.E.P. §2141.

Claims 11, 12, 15, and 23 each depend, directly or indirectly, from independent claim 1. Thus, each of these claims require an elongated flexible fluid delivery-line which includes a heating element and three or more thermal sensors.

As discussed in detail above, Ogawa does not teach or suggest such a delivery-line. Instead, the Ogawa device is a conventional fluid heater, in which fluids are passed through a

rigid casing for heating by a set of heating plates. None of the modifications of Ogawa proposed in view of Shigezawa in the Office Action (pages 8-10) cure this deficiency.

In view of this, Applicant respectfully submits that there is no proper basis for the rejections of claims 11, 12, 15, and 23 as unpatentable over Ogawa in view of Shigezawa. Applicant respectfully requests reconsideration and withdrawal of these rejections.

D. Ogawa in view of Cassidy

The Office Action rejects claims 20 and 21 under 35 U.S.C. §103(a) as unpatentable over Ogawa in view of Cassidy et al. U.S. Pat. No. 6,175,688 ("Cassidy"). Applicant respectfully traverses.

Initially, Applicant does not concede that the proposed modifications of Ogawa in view of Cassidy would have been obvious to a person skilled in the art at the time of the invention. However, even assuming, *arguendo*, that the proposed modifications are proper, Applicant respectfully submits that they fail to teach or suggest each and every limitation of the rejected claims, as required for a proper rejection under 35 U.S.C. §103(a). M.P.E.P. §2141.

Claims 20 and 21 each depend, directly or indirectly, from independent claim 1. Thus, each of these claims require an elongated flexible fluid delivery-line which includes a heating element and three or more thermal sensors.

As discussed in detail above, Ogawa does not teach or suggest such a delivery-line. Instead, the Ogawa device is a conventional fluid heater, in which fluids are passed through a rigid casing for heating by a set of heating plates. None of the modifications of Ogawa proposed in view of Cassidy in the Office Action (page 10) cure this deficiency.

In view of this, Applicant respectfully submits that there is no proper basis for the rejections of claims 20 and 21 as unpatentable over Ogawa in view of Cassidy. Applicant respectfully requests reconsideration and withdrawal of these rejections.

E. Ogawa in view of Kurucz

The Office Action rejects claim 32 under 35 U.S.C. §103(a) as unpatentable over Ogawa in view of Kurucz U.S. Pat. No. 6,175,688 ("Kurucz"). Applicant respectfully traverses.

Initially, Applicant does not concede that the proposed modifications of Ogawa in view of Cassidy would have been obvious to a person skilled in the art at the time of the invention. However, even assuming, *arguendo*, that the proposed modifications are proper, Applicant respectfully submits that they fail to teach or suggest each and every limitation of the rejected claim, as required for a proper rejection under 35 U.S.C. §103(a). M.P.E.P. §2141.

Claims 32 depends from claim 1, and therefore requires an elongated flexible fluid delivery-line which includes a heating element and three or more thermal sensors. As discussed in detail above, Ogawa does not teach or suggest such a delivery-line. Instead, the Ogawa device is a conventional fluid heater, in which fluids are passed through a rigid casing for heating by a set of heating plates. None of the modifications of Ogawa proposed in view of Kurucz in the Office Action (pages 10-11) cure this deficiency.

In view of this, Applicant respectfully submits that there is no proper basis for the rejection of claim 32 as unpatentable over Ogawa in view of Kurucz. Applicant respectfully requests reconsideration and withdrawal of this rejection.

IV. Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to

Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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